

## **REMARKS**

This preliminary amendment is presented to eliminate multiple dependencies in the claims and to place the application in better form for examination. No new matter has been added. Early examination and favorable consideration of the above-identified application is earnestly solicited.

Claims 1-17 are pending in the present application. Claims 1, 12 and 13 have been amended. Support for the amendments can be found at, for example, page 4, lines 1-6 and Examples 1-7 of the specification of the present application. Specifically, at page 4, lines 1-6, the specification describes that the carboxyvinyl polymer in the sustained release tablets of the present invention is used as the stabilizing agent and controlled release material. All the compositions disclosed in Examples 1-7 comprise carboxyvinyl polymer as the sole stabilizing agent and the sole controlled release material. This preliminary amendment is presented to place the application in better form for examination. No new matter has been added.

### **Claim Rejections under 35 U.S.C. 112**

The Examiner rejected claims 1-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that there was no written description in the originally filed specification that would exclude acidic pharmaceutical carriers other than carboxyvinyl polymer as stabilizing agents.

Since Applicants have deleted the language of "essentially free of acidic pharmaceutical carriers other than carboxyvinyl polymer as stabilizing agents" in the present amendments, the rejections become moot. As stated above, the present amendments are supported by the specification. Hence, the newly amended claims comply with the "written description" requirement under 35 U.S.C. 112, first paragraph. Therefore, withdrawal of the "written description" rejections is respectfully requested.

### **Claim Rejections under 35 U.S.C. 103**

The Examiner rejected claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Lowey (U.S. Patent 4,680,323) in view of Baker et al (U.S. Patent 4,687,660) and Seth (U.S. Patent 6,033,686).

Lowey discloses a sustained release pharmaceutical carrier comprising pharmaceutical agents, carboxyvinyl polymer and hydroxypropyl methylcellulose (HPMC), which are used to control the release of an active ingredient. The carrier can be used with a pharmaceutically agent such as pseudoephedrine HCl. As Lowey stated, using HPMC as the controlled release material of pharmaceutical formulations has been known (see col. 1, lines 34-50). Since the pharmaceutical composition claimed in the presently amended claims comprises carboxyvinyl polymer as the sole controlled release material, it does not use any HPMC as a controlled release material. In addition, as the Examiner acknowledged, Lowey does not disclose bupropion hydrochloride, which is used in the present invention.

Baker discloses a pharmaceutical controlled delivery system for beneficial agents. The pharmaceutical delivery system comprises a core containing a beneficial agent, and an osmotic enhancing agent, and a water-insoluble, water-permeable coating such as cellulose acetate surrounding the core. Baker does not disclose the use of carboxyvinyl polymer which is used in the present invention.

Seth discloses a controlled release tablet comprising a core that contains bupropion hydrochloride and conventional excipients, and a coating that consists essentially of water-insoluble water-permeable film-forming polymer such as ethylcellulose. The core is free of a stabilizer. Seth does not disclose carboxyvinyl polymer, which is used in the present invention.

Therefore, none of the references cited by the Examiner discloses a pharmaceutical composition that comprises carboxyvinyl polymer as the sole controlled release material. Hence, even if a person of ordinary skill in the art had combined the teachings of the references cited by the Examiner at the time the present invention was made, he or she would have not arrived at the present invention. Hence, Applicants respectfully request the Examiner to withdraw the rejections of claims 1-17 under 35 U.S.C. 103.

Based on the amendments and remarks above, it is believed that the pending claims are now in a condition of allowance. Early notice of such allowance is earnestly requested.

Any additional fees or charges required at this time in connection with the application may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,  
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